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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PPLICANT(s): Jose Esteve-Soler, et al.

SERIAL NO.:

10/536,782 V

ART UNIT:

FILING DATE:

11/23/05

**EXAMINER:** 

TITLE:

USE OF 2, 5-DIHYDROXYBENZENESULFONIC COMPOUNDS FOR THE TREATMENT OF DISORDERS BASED ON AN IMPAIRMENT OF NO PRODUCTION AND/OR OF

REGULATION OF EDHF FUNCTION

ATTORNEY

DOCKET NO.:

785-012246-US (PAR)

Commissioner of Patents

P.O. Box 1450

Alexandria, VA 22313-1450

## INFORMATION DISCLOSURE STATEMENT (37 C.F.R. §1.97(b)(3))

Sir:

This information disclosure statement is being filed before the mailing of a first Office Action on the merits.

The following information is being disclosed to the Patent and Trademark Office as information that may be material to the examination of the above-identified patent application. Applicants' Attorney is aware of the following references:

"PHARMACOLOGICAL ASPECTS OF ERECTILE DYSFUNCTION", John A. Thomas, Jpn. J. Pharmacol. 89, 101-112 (2002)

"DOBESILATE ENHANCES ENDOTHELIAL NITRIC OXIDE SYNTHASE-ACTIVITY
IN MACRO- AND MICROVASCULAR ENDOTHELIAL CELLS", Christoph
Suschek, et al., British Journal of Pharmacology (1997) 122,
1502-1508

"EFFECTS OF CALCIUM DOBESILATE ON THE SYNTHESIS OF ENDOTHELIUM-DEPENDENT RELAXING FACTORS IN RABBIT ISOLATED AORTA", E. Ruiz, et al., British Journal of Pharmacology (1997) 121, 711-716

"CONSEQUENCES OF REDUCED PRODUCTION OF NO ON VASCULAR REACTIVITY OF PORCINE CORONARY ARTERIES AFTER ANGIOPLASTY: IMPORTANCE OF EDHF", Catherine Thollon, et al., British Journal of Pharmacology (2002) 136, 1153-1161

"ORAL DRUG DELIVERY, SMALL INTESTINE & COLON", Joseph Fix, pages 698-742

"PHARMACEUTICS, The Science of Dosage Form Design", Edited by M.

E. Aulton, coverpage

"A NITRIC OXIDE-LIKE FACTOR MEDIATES NONADRENERGIC-NONCHOLINERGIC NEUROGENIC RELAXATION OF PENILE CORPUS CAVERNOSUM SMOOTH MUSCLE", Noel Kim, et al., Volume 88, July 1991, 112-118

"HANDBOOK OF PHARMACEUTICAL SALTS, Properties, Selection, and Use", P. Heinrich Stahl, et al., International Union of Pure and Applied Chemistry (IUPAC), Table of Contents

"ENDOTHELIUM-DEPENDENT HYPERPOLARIZATION AS A REMOTE ANTI-ATHEROGENIC MECHANISM", Stavros Selemidis, et al., TRENDS in Pharmacological Sciences, Vol. 23, No. 5, May 2002, pages 213 -220

"CHARACTERIZATION OF ENDOTHELIUM-DERIVED HYPERPOLARIZING FACTOR IN THE HUMAN FOREARM MICROCIRCULATION", Julian P. J. Halcox, et al., Am J Physiol Heart Circ Physiol, 280:H2470-H2477, 2001

"ENDOTHELIUM-DERIVED HYPERPOLARIZING FACTOR: IDENTIFICATION AND MECHANISMS OF ACTION IN HUMAN SUBCUTANEOUS RESISTANCE ARTERIES",

CIRCULATION, Journal of the American Heart Association, Paul Coats, et al., Circulation 2001;103;1702-1708

"HUMAN CORONARY ARTERIOLAR DILATION TO ARACHIDONIC ACID DEPENDS ON CYTOCHROME P-450 MONOOXYGENASE AND Ca 2+-Activated K+ Channels", Hiroto Miura, et al., CIRCULATION RESEARCH, Journal of the American Heart Association, Circ. Res. 1998;83;501-507

"NITRIC OXIDE: A NEW PARADIGM FOR SECOND MESSENGERS", James F. Kerwin, Jr., et al., Journal of Medicinal Chemistry, 1995, Vol. 38, No. 22, pages 4344-4362

"IN VITRO EFFECTS OF CALCIUM DOBESILATE ON THE RESPONSIVENESS OF SPONTANEOUSLY DIABETIC RAT AORTA", Mercedes Sanz, et al., Jpn. J. Pharmacol. 78, 391-394 (1998) pages 391-394

Copies of these references are enclosed together with a Form PTO-1449.

The filing of this Statement is not to be construed as a representation that a search has been made regarding the claimed invention (37 C.F.R. §1.97(g)) or that no other possible material information exists. In addition, the filing of this Information Disclosure Statement is not to be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability (37 C.F.R. §1.97(h)).

The Commissioner is hereby authorized to charge payment for any fees associated with this communication or credit any over payment to Deposit Account No. 16-1350.

Respectfully submitted,

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## CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service on the date indicated below as first class mail in an envelope address to the Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Page No.: 1 of: 1

INFORMATION DISCLESURE

IAPA CITATION TORS

WPATENT APPLICATION

Docket No.: 785-012246-US (PAR)

Serial No.: 10/536,782

Applicant(s): Jose Esteve-Soler, et al.

te) Filing Date: 11/23/05

Group:

<b>&gt;</b>	(Substitute)		Filing Date: 11/23/05	Group:			
-			U.S. PATENTS				
finitials	Patent Number	Issue Date	Name	Class	Sub- class	Filing date	
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"			ECTILE DYSFUNCTION", John A. Thomas,			2002)	
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"	PHARMACEUTICS. The S	Science of Dosage	Form Design", Edited by M. E. Aulton, cove	rpage			
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	CORPUS CAVERNOSUM SMOOTH MUSCLE", Noel Kim, et al., Volume 88, July 1991, 112-118						
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Examin	er's Signature:			Date Considered:			

Initial if reference was considered, whether or not citation is in conformance with MPEP. Mark through citation if not considered.

Include a copy of this citation form with your next correspondence to the Applicant(s).

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